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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/281,430	03/30/99	PARIKH	121-160

HM22/1003

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EXAMINER	
WARE, T	
ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/281,430	PARIKH ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- Th MAILING DATE of this communication app ars on the cover sh t with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-12,14,17-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12,14,17-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-21-01 has been entered. Claims 8-12, 14, 17-20, and 22-25 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> a. The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-12, 14, 17-20, and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims directed to formation of droplets having an average droplet size of 2 to 10 microns do not appear to be enabled.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be

considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art.

(a) In order to utilize the system as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing the instant compositions to arrive at droplet size would have to be resolved by the practitioner for the reasons discussed below.

(b & c) The specification states that the instant compositions of the invention give emulsions having an average droplet size of 2 to 10 microns. However, the specification lacks a reasonable level of guidance for a composition/method for said treatment, and working and/or prophetic examples are inadequate. Applicant has not taught or defined how the invention arrives at determining the size of the droplets. In other words, the size of the droplets in the GI of an organism has not been demonstrated.

(d) The nature of emulsions is complex.

(e & f) Although the art provides a certain level of guidance with regards to the formation of the instant emulsions, these teachings do not provide sufficient guidance where the specification is lacking. Upon ingestion of a composition, it becomes emulsified in the GI of the organism ingesting the composition. Thus the “droplets formed” would be pulled apart to smaller sizes.

(g) The claims are broad because there is no guidance for arriving at the size of the droplets in the GI.

(h) The level of skill of those in the art involving emulsions is high.

The skilled practitioner would first turn to the instant specification for guidance in determining the droplet size formed by the compositions, as claimed. However, the specification does not provide sufficient guidance for using the instant compositions, as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art demonstrates that administration of the instant compositions results in emulsification of the droplets in the GI of the organism ingesting the composition. Thus the "droplets formed" would be pulled apart to smaller sizes. Finally, said practitioner would turn to trial and error experimentation to make/use the instant compositions, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> b. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 8-12, 14, 17-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al (5,342,625; hereafter '625) in view of Shively (5,407,683; hereafter '683).

'625 teaches a non-aqueous, microemulsion pre-concentrate composition comprising a cyclosporin, 10 to 80% of a hydrophobic component (C 8, L 58- C 9, L39 and examples), 20 to 80% or a surfactant phase (C 9, L 40- C 12, L 6 and examples) and a hydrophilic component, such as ethanol and/or 1,2 propylene glycol. '625 teaches that the particle size of the microemulsions obtainable from the pre-concentrate is about 150-2000 Å (15-200 nm) when added to water.

'625 also teaches that cyclosporin is used in the treatment of cancer as an agent for reversing anti-neoplastic agent resistance in tumors.

'683 is relied upon for showing that taxanes are well-known in the art for the treatment of cancer. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine a taxane with the composition of '625 in an effort to reduce the growth of a tumor with the motivation that taxanes are known to inhibit tumor growth and that cyclosporin would prevent resistance to the taxane. Also, since it appears that the compositions of '625 are the same as those of the instant claims, the drug bioavailability of the instant claims would be inherent within such a combination since products of identical chemical composition can not have mutually exclusive properties. In other words, a chemical composition and its properties are inseparable (MPEP 2112.01).

Response to Arguments

6. Applicant's arguments filed 8-21-01 have been fully considered but they are not persuasive. Applicants argue that the instant claims are patentable over '625 and '683 since '625 does not teach that emulsions having droplets within the instant ranges are formed from the pre-concentrates of '625. This is not found persuasive since the specification does not appear to be enabling for pre-concentrates that form droplets within the instant ranges and because it is not understood how such an emulsion would maintain the instant droplet size in the GI. It would seem that such an emulsion would become emulsified in the GI to form droplets smaller than the instant range. Furthermore, no evidence has been submitted demonstrating that a taxane administered in the composition of '625 would not have a bioavailability within the instant range.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

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September 27, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600